

REVIEW ARTICLE

Point-of-Care Testing in Hospitals and Primary Care

Ralf Junker, Harald Schlebusch, Peter B. Lupp

SUMMARY

Background: Many medical laboratory tests can now be done near the patient (point-of-care testing, POCT), ranging from basic blood glucose measurement to complex coagulation testing. Switching from conventional laboratory testing to POCT shortens the time to decision-making about further testing or treatment, as delays are no longer caused by specimen transport and preparation, and the test results are rapidly available at the point of care. Better medical outcomes and lower costs may ensue.

Method: Selective literature review.

Results: The available methods and equipment enable persons not specially trained in laboratory medicine to perform high-quality laboratory testing at the point of care, under certain conditions. Before POCT is introduced in a hospital or outpatient practice, a cost-benefit analysis should be performed, because the introduction is costly and requires a certain amount of organizational work especially for quality management. The potential medical and economic benefits should be assessed individually in each case.

Conclusion: POCT for certain applications is a useful complement to conventional laboratory testing. The future utilization of POCT will depend not only on technical advances, but also on developments in costs and reimbursement.

The expression “point-of-care testing” (POCT) refers to the use of the procedures of laboratory medicine in the immediate vicinity of the patient (*Box 1*). This is a recent development in laboratory medicine driven by the clinical need to obtain investigation results without delay. POCT has been facilitated by the increasing miniaturization of laboratory instruments and procedures. The key advantages of POCT are that it dispenses with sample transport to the laboratory and sample preparation. In addition, the results are immediately available at the patient’s bedside. This brings a time advantage, allowing results to inform urgent decisions about further diagnostic and therapeutic procedures. The European market for POCT systems has grown rapidly in the last ten years. The German market is now almost 0.9 billion Euros, corresponding to about a third of the total market for in vitro diagnostic testing (e1). The present review describes current diagnostic applications of POCT, together with special features which must be born in mind when applying this approach in hospitals or practices (*Table 1*). This is intended to offer the reader a critical understanding of the issues, especially the medical, organizational and economic advantages and disadvantages.

Methods

The review is based on a selective literature search, together with the first textbook on POCT in the German language (1) and additional Internet sources. The literature search covered Medline/PubMed from January 2000 to January 2009. The key words were point-of-care testing/near patient testing/bedside testing, each in conjunction with hematology/clinical chemistry/coagulation etc.. The following selection is limited to clinically important parameters measurable in blood for which there are already several different point-of-care procedures. Urine tests (e.g. pregnancy tests and drug screening) and stool tests (for example, fecal occult blood) will not be discussed. Microbiological point-of-care testing will also be omitted, as there has been a recent review on this subject in *Deutsches Ärzteblatt International* (2). Manufactures of diagnostic equipment or tests will not be mentioned.

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BOX 1

Laboratory investigations by POCT take place:^{*1}

- Outside the laboratory
- In the immediate vicinity of the patient
- Without sample preparation and generally without pipetting steps. The test material is usually whole blood.
- With measuring instruments intended or used for single samples
- With “ready-to-use” reagents
- Without the necessity of in-depth medical technical qualification for operating the instrument
- With rapid availability of the results
- With the immediate deduction of therapeutic consequences from the results

^{*1} modified from (1, 17, e2)

Areas of use, analyses and equipment formats

Although POCT systems are mainly used in hospitals and medical practices, they are also of importance in other areas (*Table 2*). There is a large area of overlap between the areas of use and the different methods. For example, instruments to measure blood glucose and Quick/INR were originally aimed at self-monitoring, but are now also used in hospitals and practices. Lipid assays are also performed in pharmacies.

However, a test performed without a medical indication cannot be strictly described as POCT.

Blood gas and glucose analyses are long established and point-of-care assays are now available for more than 100 parameters (3).

On the other hand, no cell-related analyses beyond basic diagnostic testing (for example, identification of lymphocyte subpopulations) are available as POCT. Moreover, there are no POCT procedures which require direct expert interpretation (such as immunofluorescence). In other words, POCT is largely restricted to automatically measurable parameters. Some individual analyses are described in *Box 2*.

The modern techniques of microfluidics and micro-sensorics have made it possible to develop a totally new concept of test systems and this is especially reflected in so-called “handheld” instruments. These instruments make it possible to determine one or several parameters quantitatively in different combinations, either sequentially or in parallel. One example is the determination of blood gases in combination with electrolytes or cardiac markers. These instruments have automatic calibration programs, mostly together with a control system. This monitors the analytical steps in the process and can also be used for data processing and network formation. On the other hand, table or bench top

instruments can often be regarded as miniaturized forms of classical laboratory instruments. Many of these systems utilize so-called unit use reagents. This means that the reagents are provided as individual portions for each measurement and are consumed by a single test. This is particularly the case for instruments for the quantitative measurement of individual parameters, such as blood glucose, but is also used for more demanding cassette or chip systems for the simultaneous measurement of a number of parameters.

Legal conditions for licensing, operation and quality assurance

In vitro diagnostic tests—both conventional tests and POCT procedures—can only be marketed if the product has been awarded a CE mark. This confirms conformity with the European directives for in vitro diagnostic testing (IVD directive), but does not permit any statement about the test’s diagnostic reliability (18). According to the German Medical Device Regulations and the German Law on Liability, the same conditions apply to conventional laboratory analyses as to POCT. Although the test manufacturer is responsible for determining and providing the performance data, the user is responsible for checking whether performing the POCT test is suitable for its diagnostic or monitoring purpose, and technologically up to date. The latter is laid down by the legislator, the German Regulations on Medical Devices and harmonized European standards, but must always be orientated towards the objective situation (19). Thus, in an acute situation, the immediately available result from a POCT test with a high, but medically defensible, coefficient of variation may be of more benefit than a qualitatively better result which is only available on the following day (20).

The 2008 Directive of the German Medical Association on the Quality Assurance of Tests in Laboratory Medicine (RiliBÄK 2008) does not stipulate any special regulations for POCT in comparison to those for a medical laboratory, the only exception being the unit use systems (e2). Part A of the RiliBÄK contains the fundamental requirements for quality assurance, such as the preparation of a quality handbook (*eBox 1*) and applies both in hospitals and in practices. Part B1 contains the specific requirements for the quality assurance of quantitative laboratory tests; there are as yet no directives for qualitative tests (*eTable 1*). The necessary documentation is listed in *eBox 2*.

There is also in principle no difference between POCT and conventional laboratory diagnostic testing with respect to the possibility of pre- and post-analytical errors. Thus, the whole diagnostic process must be considered in quality assurance, just as in classical laboratory medicine (*eBox 3*) (21, e2).

Application in hospitals and practices

The available analytical spectrum and the possibility of networking POCT systems and of central monitoring have made it possible to develop new approaches to clinical laboratory medicine—some of which are of

TABLE 1

Central issues before and during the performance of point-of-care testing

Medical result	Procedure	Quality	Financing
<ul style="list-style-type: none"> – Diagnostic advantage? – Organizational advantage? 	<ul style="list-style-type: none"> – Where, how and who? – IT – Hygiene 	<ul style="list-style-type: none"> – Technical test quality – Legal requirements, e.g. RiliBAK directive – Pre- and post-analytics – Accreditation 	<ul style="list-style-type: none"> – Hospital: daily rates and DRGs – Practice: Reimbursement systems (in Germany: EBM/GOA)

doubtful value. These range from simple extension of the analytical spectrum, to transferring almost all laboratory services to an external provider with the exception of emergency analyses with POCT units.

If POCT is to be successfully implemented, it is absolutely essential that there should be suitable management structures, with clearly defined areas of responsibility (*eBox 4*) (22, e3). In hospitals, it has been found to be useful to set up a POCT coordination office, managed by the central laboratory. The main role of this is to fulfill the requirements of quality management (e3). Another condition for a successful POCT system is that there should be a computer network of the instruments in decentralized use with a central information system (for example, a hospital or laboratory information system) (*Figure*) (23, 24). This may allow reliable documentation of the results, optimization of quality assurance, and proper calculation of cost-effectiveness.

On the other hand, much less effort and expense are needed when introducing POCT systems into medical practices. There are fewer emergencies here and more time pressure for organizational reasons. Patient satisfaction and compliance are more important. Thus, typical investigations performed in practices include determination of the blood count before chemotherapy, CRP measurement before antibiotic treatment, HbA_{1c} determination in diabetics and BNP measurement when monitoring patients with heart failure. Two of the important preconditions for using POCT successfully are familiarity with the technology and proper quality as-

surance. This applies particularly to “real” laboratory investigations which have simply been shifted into the practice (for example, measurement of blood counts).

Medical and organizational aspects

While there are often numerous clinical studies on the medical performance of individual laboratory parameters and the technical evaluation of new POCT systems is often available in good time, there is little published data about whether the significance of a medically important laboratory parameter increases if it is measured at the bedside, or whether this is unnecessary.

One of the reasons for this is that the successful use of POCT procedures greatly depends on the setting. The critical issues in acute departments of large hospitals are not the same as those in small hospitals (for example, outsourcing, restrictions in laboratory working hours). It has for example been shown that the period that emergency patients spend in hospital outpatient departments before being admitted as inpatients, as well as the subsequent medical outcome, are independent of whether the laboratory screening took place at the POC or in the hospital laboratory. The explanation for this is that it is not the laboratory which determines the time course, but other diagnostic procedures, such as imaging, not to mention checking bed capacities (20, 25). However, the medical or organizational advantages of POCT are plausible in other cases, even without scientific proof. These include glucose determination in emergency medicine or the blood count in an oncology practice.

TABLE 2

Areas of use for point-of-care testing

Area of Use	Inpatient care	Outpatient care	Special areas	Patient self-monitoring	Relative medical indication
Areas of use	<ul style="list-style-type: none"> – Operating theater – Intensive care ward – Functional areas – Emergency admission – Special outpatient clinics – General wards – Outside lab times – Hospitals without a central laboratory 	<ul style="list-style-type: none"> – Medical practice – House visits – Emergency medicine – Outpatient nursing care 	<ul style="list-style-type: none"> – Sports medicine – Civil protection – Military 	<ul style="list-style-type: none"> – Glucose monitoring – Anti-coagulant monitoring 	<ul style="list-style-type: none"> – Sports studio – Tests from pharmacy (e.g. lipid status) – Home testing (apart from glucose and anticoagulants)

BOX 2

Selected aspects of point-of-care testing (POCT)

● Blood gases, acid-base equilibrium and electrolytes

pO_2 , pCO_2 and pH are measured electrochemically or optically. Base excess, standard bicarbonate and other parameters are calculated. Depending on the type of instrument, CO oximetry (multiwavelength photometry), procedures to determine electrolytes (for example, Na, K, iCa, iMg; ion-specific electrodes) and clinical chemistry parameters (for example, lactate; ion-specific electrodes) may be integrated, so that multifunctional blood gas analyzer (BGA) systems largely cover vital parameters. With maintenance-free cassette systems, all the mechanical parts and the reagents lie within an easily changed cassette.

● Glucose

Point-of-care determination of glucose usually employs small mobile instruments with enzymatic reactions, followed by photometric or electrochemical detection. Additional electrodes may compensate for interfering factors in blood or the effect of hematocrit (Hct). The measured values may differ strongly between different instruments, or even between different serial numbers of the instrument. This is mainly due to the use of different enzymes and differences in the quality of the instruments and test strips. For this reason, the guidelines of the German Diabetes Society specify that diabetes mellitus may only be diagnosed with glucose values measured with a quality controlled laboratory method (4, 5).

● Clinical chemistry

Aside from test systems for the determination of individual clinical chemistry parameters, there are complete systems covering a wide analytical spectrum. However, these are not widely used, as the purchasing and running costs are high (6). Use of POCT is mostly for organizational reasons. The test procedures to determine enzymes and substrates (creatinine, urea, GOT, GPT, etc.; dry chemistry, ion-specific electrodes) frequently differ from the methods used in the laboratory (7).

● CRP

Point-of-care determination of CRP is used in hospitals and practices for the rapid evaluation of the necessity of antibiotic therapy. However, it is controversial whether this leads to more specific use of antibiotics (8). The measurements are usually performed on automated immunoturbidimetric systems, which may exhibit considerable differences in analytical sensitivity and precision in the lower concentration range.

● Lipid metabolism

Point-of-care determination of the parameters of lipid metabolism is mainly performed in pharmacies, but less so in practices or hospitals. Some studies from the USA have shown that this has an educative effect. As the test was readily available, the results were discussed at once and appropriate drugs were sold immediately, and LDL cholesterol was regularly reduced. The pharmacist initiated and monitored the treatment himself (9), which is not possible in Germany.

● Bilirubin

Point-of-care determination of bilirubin is mostly performed during the diagnosis of hyperbilirubinemia in neonates. The instruments for direct photometry in serum or plasma are mostly simple filter photometers, which measure the absorption of plasma. Bilirubin can also be determined directly by photometry (multi-wavelength measurement) using the CO oximetry module in some BGA instruments.

● Hematology

Hemoglobin (Hb) measurements are often a component of the BGA. The determination uses the azide methemoglobin method or is based on the Hb absorption pattern in the diode array mode. Alternatively, a conductivity method can be used to determine Hct. On the other hand, a complete blood count, with or without leukocyte differentiation, is rarely performed at point-of-care. The available instruments are often miniaturized laboratory machines and use the same technology (lysis, measurement of resistance or impedance). In pediatrics and oncology, the demands on machines for POCT testing are very high, as reactive lymphoid and precursor cells are difficult to classify by morphology and erroneous results may be obtained (11, 12).

● Hemostaseology

Simply operated handheld instruments are mostly used to determine Quick values, INR, PTT and ACT in whole blood. Coagulation is triggered with thromboplastin or with contact activators. Detection is based on clot formation in the sample. It is difficult to compare the results with different systems, as different activators and detection procedures are used. The procedure reacts sensitively to various factors, including drugs, metabolic disorders and temperature fluctuations (13).

● Cardiovascular diagnostic testing

Numerous test systems are available for the immunological determination of cardiac troponins, BNP and D-dimers. These systems range from handhelds for individual determinations to bench instruments for the combined analysis of different cardiovascular markers. In outpatient clinics, the determination of (NT-pro) BNP and D-dimer can be used for prescreening and help to exclude heart failure, deep vein thrombosis or pulmonary embolism. This reduces the number of more demanding tests and saves costs. However, it does not replace confirmation of the diagnosis with established imaging procedures. As the troponin concentration may still be under the detection threshold in the first few hours after the acute event, a negative test result does not reliably exclude an acute myocardial infarction (14–16). POCT procedures are primarily used for organizational reasons.

Cost-effectiveness

There are as yet no published cost-effectiveness analyses of POCT, in particular, not for the German-speaking area, with its special regulations on financial reimbursement of medical services. It is however generally the case that POCT procedures are markedly more expensive than conventional laboratory tests. Aside from the greater costs for the instruments and reagents, additional working hours are needed and this may have to be reflected in the number of jobs in the hospital or practice.

The fixed costs in the laboratory are often largely unchanged. There may be no fixed laboratory costs at all in a medical practice. As the POCT costs in hospital are reimbursed with the daily hospital rate or the G-DRG revenue, they must be evaluated from an objective medical point of view and also with respect to other feasible equivalent health care concepts. On the one hand, the possibility of economic and organizational improvements must be considered, for example, by optimizing the time course of work in the central laboratory or in the outpatient clinic. On the other hand, payment in medical practices largely depends on services delivered, so that the individual POCT analysis is charged for. The medical account system allows fees for POCT analyses in principle, but these reflect the real costs only in rare cases (e4, e5). This particularly applies to basic services with low reimbursement rates, which may nevertheless be essential for operating the practice in specialized areas (e Table 2).

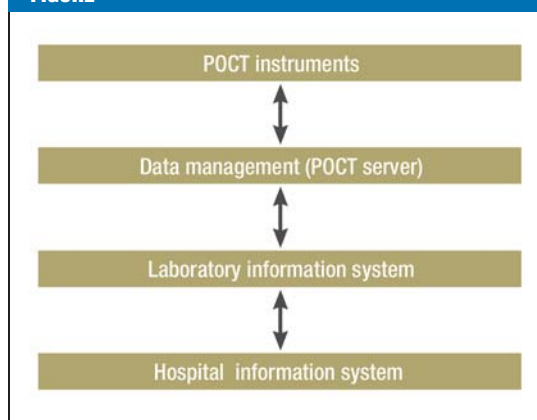
Economic considerations are also relevant at a higher level. If screening with laboratory tests could reduce the use of expensive imaging procedures, this might lead to overall savings in the health system—but to a reduction in the revenue in other diagnostic disciplines.

Conclusion and outlook

A large number of laboratory tests are now available in different POCT formats, so that it is often possible to perform high quality laboratory diagnostic testing, even without a high degree of expertise in medical technology. This has allowed the development of new approaches to laboratory care in medical practices and in hospitals. Nevertheless, the justification for POCT analysis must be scrutinized in individual cases and compared with other organizational solutions, with the aim of adequately exploiting the medical potential and avoiding waste. In the interest of optimal patient care, it must also be remembered that uncritically selected and inexpertly used POCT methods cannot replace the expertise of a medical laboratory.

At first glance, the increasing use of POCT procedures appears to be in contrast to current tendencies towards centralization in laboratory medicine. However, on closer examination it becomes clear that the use of POCT can create a new balance between rapid acute on-site diagnostic testing and consolidated economic routine and special analysis in a large regional hospital laboratory or practice for laboratory medicine.

FIGURE



The data management system is on a separate POCT server and is also used as a control module for the instruments, data and quality management, and reagent administration. The measured values are designated separately as "POCT" and integrated into the cumulative laboratory report (24). The network also permits complete recording of all POCT measurements performed, so that they can be assigned to the appropriate cost centers. The POCT-1-A is becoming increasingly established as the communication protocol for newly developed systems. Network software may be purchased from the manufacturers of diagnostic materials and is then system specific. Alternatively, it may be purchased from other firms and can then be used for several systems (25).

Medical practices are able to offer POCT systems as an adjunct to traditional laboratory analysis. This is partly for organizational reasons, but also because practicing physicians increasingly regard themselves as service providers.

The potential of currently available tests is far from being exhausted, but POCT procedures are not spreading as rapidly in Germany as they did at first. Although there were two figure increases in the 1990s, the German POCT market only increased by 1% in 2007—in contrast to conventional laboratory testing, which increased by just under 3% in the same year (€1). One possible reason may be that service provision is simply unaffordable in some areas. Thus, to a large extent, POCT is currently an adjunct to the medical laboratory. However, in the longer term, increasing miniaturization of the technologies and more rapid measurement procedures will make it a serious alternative to conventional laboratory diagnostic testing.

Conflict of interest statement

Prof. Luppä has received lecture fees from IL, OCD, Roche, and Siemens. He has also received support for studies from Roche and Siemens. Prof. Schlebusch and Prof. Junker declare that there is no conflict of interest in the sense of the guidelines of the International Committee of Medical Journal Editors.

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KEY MESSAGES

- POCT is a modern variant of laboratory medicine. Its technical development has been largely determined by the miniaturization of instruments and procedures, as well as the use of modern information technologies.
- Aside from the determinations of blood sugar and blood gases, a wide variety of clinical chemical, immunological, hematological and hemostaseological procedures are now available.
- POCT is of considerable medical significance in providing emergency analyses in potentially fatal situations. In intensive medical care, not only purely medical, but also organizational aspects are important. The organizational aspects are clearly more important in outpatient clinics and patient admission.
- The aim of POCT is to accelerate diagnostic and therapeutic processes and thus to reduce the period spent by the patient in the hospital, intensive care ward or operating theater, as well as reducing treatment costs by adequate structure of the therapy, optimal patient monitoring and avoiding complications.
- Quality assurance of POCT procedures is in accordance with the directive of the German Medical Assembly on the Quality Assurance of Laboratory Medical Tests.

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eBOX 1

Content of the Quality Handbook^{*1}

- Quality policy
- Organization of POCT
- Responsibilities and qualifications
- Employee training
- Instruments and test procedures
- Pre- and post-analysis
- Performance of quality control
- Procedure for errors or uncertainties

^{*1} According to the 2008 Directive of the German Medical Association (e2)

eBOX 2

Recording of individual measurements on control samples^{*1}

- Type of measurement and serial number
- Date and time of the measurements
- Identification of the control sample (e.g. manufacturing designation, batch no.)
- Parameter (system, analyte, unit)
- Measured value for control sample
- Target value for control sample
- Relative or absolute deviation from target value
- Evaluation according to Table B1, column 3 of the Directive of the German Medical Association
- Name and signature of the user

^{*1} According to the 2008 Directive of the German Medical Association (e2)

eBOX 3

Important pre- and post-analytical errors in POCT diagnostic testing^{*1}

- **Pre-analytical errors**
 - Unsuitable indication for the performance of the test
 - Lack of preparation of the patient (e.g., fasting before functional tests, posture, position)
 - Inappropriate sampling times (for example, for functional tests, circadian rhythm)
 - Lack of information about the patient's condition (for example, drug history, body temperature)
 - Inappropriate sampling technique (for example, sample diluted by compression during collection of capillary blood)
 - Wrong or missing additives to blood
 - Unsuitable test material (hemolytic, icteric, lipemic)
 - Inappropriate sample handling (e.g. inadequate mixing of sample with additives)
- **Post-analytical errors**
 - Inadequate technical validation
 - POCT results not designated in cumulative findings, abnormal results not marked
 - Erroneous assignment of the results or other errors in data storage

^{*1} Factors influencing these errors and problems include the setting (practice, hospital, etc.) and the extent to which the instrument is within a network. Transport, storage and centrifugation are irrelevant for POCT. Evaluation of the test material is mostly unnecessary, as whole blood is used. However, correct collection of the sample is of the greatest importance in the pre-analytical process (1).

eBOX 4

Possible distribution of the areas of responsibility for POCT^{*1}

- **Hospital administration**

Hospital management should convene a POCT committee, to ensure that POCT is properly organized with respect to medical and economic issues, and that it is performed in accordance with legal regulations on quality assurance. Hospital and laboratory management should participate in this committee, together with other groups with interests in POCT. The committee should be managed by a POCT coordinator.

- **Medical management**

It is expected that the medical management of the hospital will specify medical objectives and provide the necessary rooms, personnel and finances for POCT. The laboratory management is responsible for formulating quality requirements and objectives, as well as for developing a plan for selecting and evaluating the performance of POCT instruments.

- **POCT Committee**

The POCT committee should include representatives of the hospital departments involved, the nursing service, the central laboratory, as well as administration, the pharmacy and medical engineering department. This committee should also include POCT managers from the individual clinical areas, who act as a link between POCT coordination and the final users of the POCT instruments.

According to DIN EN ISO 22870, the multidisciplinary POCT must make and implement all decisions for the use of POCT procedures. The clinical demands (indications) for POCT must be considered, its financial consequences (cost-benefit considerations), technical feasibility (resources) and its integration in the functional processes in each department must be considered. The central responsibilities of the committee include the evaluation and selection of instruments and systems for POCT, the distribution of responsibilities and authorizations for the employees within the hospital departments, extending to the organization of quality control in accordance with the legal requirements and the corresponding procedures. Long-term satisfactory solutions can only be achieved if all members of the POCT committee—with their different interests and views—are actively involved in the decision process and in solving any problems of principle or conflicts which may arise. All members of a new POCT committee must understand how essential it is and act with commitment and patience, to ensure that the committee is and will remain capable of performing its mission. The committee should not only meet when there are urgent issues to discuss, but should have regular sittings—at least once a year.

- **POCT Coordinator**

A qualified laboratory employee should be nominated as the POCT coordinator. The POCT coordinator acts in accordance with a description of his area of responsibility and authorization. This description must be in writing and confirmed by hospital management. The POCT coordinator regulates interactions between the employees and departments. He organizes the implementation of the decisions reached in the POCT committee and helps to administer POCT.

- **Medical service**

Recognizing indications and interpreting test results falls in the responsibility of the physicians. The performance of the test may also be in the responsibility of the physicians, depending on the organization of the individual hospital.

- **Nursing service**

Nursing staff play a most important role in POCT. Their duties are defined by the organizational structure and the staff infrastructure in each clinical department and include preparation of patients, sampling, and performing measurements. They are also responsible for quality assurance and the whole area of logistics linked to POCT—for example, ordering and disposal. The necessary time may have to be incorporated into the personnel plan.

^{*1} modified from (20, 23)

REVIEW ARTICLE

Point-of-Care Testing in Hospitals and Primary Care

Ralf Junker, Harald Schlebusch, Peter B. Lupp

eTABLE 1

Quality control^{*1}

	Laboratory procedure	Unit use procedure
Internal	<ul style="list-style-type: none"> • Single measurement of control sample at least twice per 24h and not later than 16h • Single measurement of control sample after each intervention in the measurement system <ul style="list-style-type: none"> – for example, when restarting the instrument after it has been fully switched off, – after calibration by the user, – repair or servicing, – change in reagent batch • Alternate use of control samples with different concentration ranges • Evaluation according to Table B1, column 3 of the 2008 Directive of the German Medical Association. <ul style="list-style-type: none"> – If the given limit is exceeded, the procedure can nevertheless be approved for further measurements if the reasons are documented. – At the end of the control cycle (normally one month), the relative root mean square of the measurement deviations must be calculated from the results of the single measurements of the control samples. If the set limit is exceeded, the procedure must be blocked for further measurements, until additional measures have been taken to ensure that it works. However, this case can only occur if several of the individual measurements of the control sample during the control cycle were outside the given limit. • All results of internal quality control must be documented and stored for 5 years, together with approval, blocking notices, and the corrective measures taken. Additionally, the measured values for the control sample should be shown graphically. 	<ul style="list-style-type: none"> • Testing of reagents and measuring instruments according to the manufacturer's instructions for quality control. If these differ from the 2008 Directive of the German Medical Association, the stricter criteria are to be applied. • At least one single measurement of a control sample must be performed per week for POCT instruments which daily use an electronic or physical standard or an integrated functional test to prevent issuing false results. Additional controls are necessary after: <ul style="list-style-type: none"> – calibration by the user, – repair or servicing, or – change of reagent batch. • If the instrument has no electronic or physical standard and there is no integrated check of instrument function, a single measurement of a single sample must be performed at least twice in 24h—as with all other instruments. • Calculating the root mean square of the measurement deviations or the graphic illustration of the results are not necessary. • Documentation is as with a conventional laboratory procedure.
External	<ul style="list-style-type: none"> • Each organizational unit must take part in four interlaboratory comparisons per year for the parameters they measure. An organizational unit is defined as a separate area (functional unit) of a hospital, with the following characteristics: <ul style="list-style-type: none"> – a fixed group of users (physicians, nurses), – a pool of sites of measurement and measuring instruments restricted to this area, – operation of the sites of measurement only by the defined group of users. – Examples are central laboratories, operating room, intensive care wards, delivery rooms or pulmonary function laboratories. • Evaluation according to table B1, column 5 of the 2008 Directive of the German Medical Association • The obligation to participation in the interlaboratory comparison can only be dispensed with when different organizational units and the central laboratory are combined into a single organizational unit by official instructions from the hospital management for laboratory medical analysis. In such a case, it suffices if the central laboratory participates. 	<ul style="list-style-type: none"> • As with conventional laboratory procedures, there is an obligation to participate in interlaboratory comparisons. • There is no obligation for <ul style="list-style-type: none"> – physicians in practice outside hospitals or in medical services without a central laboratory, or for – hospitals if the central laboratory bears the responsibility for internal quality assurance and determines the parameter itself. In other words, the central laboratory takes part in the interlaboratory comparison itself for this parameter. The method of analysis used in the central laboratory and with POCT must not be identical.

^{*1} According to the 2008 Directive of the German Medical Association (e2)

eTABLE 2

Accounting of Point-of-Care Laboratory Analyses (POCT) according to GOÄ and EBM*¹

	EBM 2009				GOÄ (Chapter M)							Costs POCT*4	
	Note	Code	Cost	Surcharge, own laboratory	Note	M I code	Price, single	M II code	Price, single	M III code	Price, single	Price reagent, from about	Price in-strument, from about
Hemogram		32120	0.50 €					3550	3.50 €			0.60 €	8 500 €
Quick, capillary		32114 32026 ²	0.75 € 4.70 €			3530	6.99 €	3607	2.91 €			a) 3.30 € b) 5.00 €	950 € 5 000 €
Glucose		32057 32025 ²	0.25 € 1.60 €	0.80 € ³		3514	4.08 €	3560	2.33 €			a) 0.50 € b) 0.50 €	25 € 500 €
GPT		32070	0.25 €	0.80 € ³		3516	4.08 €	3595H1	2.33 €			1.50 €	2 500 €
βHCG	SST	32132	1.30 €		SST	3528	7.58 €					0.50 €	Test strips, qualitative
Troponins	also instrumental	32150	11.25 €		RT	3511	2.91 €			A3732	11.66 €	12.00 €	2 500 €
(NT-pro) BNP		32097	25.00 €		RT	3511	2.91 €			A4069	29.15 €	25.00 €	2 500 €
D-dimer		32117	4.60 €		RT	3511	2.91 €			3938	20.98 €	12.00 €	2 500 €

*¹(Selection) (e4, e5).

² Reimbursement only if service provided in the practice of a statutory health insurance physician, who has ordered the test. Service provision is assumed if the result of the investigation is available within one hour of taking the sample. This is not chargeable when work performed by group laboratories.

³ Surcharge when performed with preportioned reagent portions ... within own practice as individual determination (e4, e5)

⁴ a) Home testing system; b) Systems for clinical use, can be networked; SST, pregnancy test; RT, strip test; M I, availability service in the practice; M II: can also be ordered as service; 3511: studies on body materials with preprepared reagent portions; POCT prices without considering working times, control material, storage, documentation etc., catalogue prices of a large German provider of medical devices or the test manufacturer.